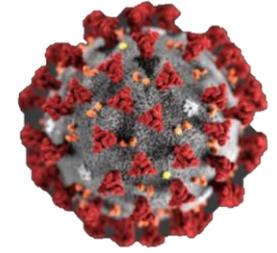


# New Hampshire Coronavirus Disease 2019 Weekly Call for Healthcare Providers and Public Health Partners



May 27, 2021

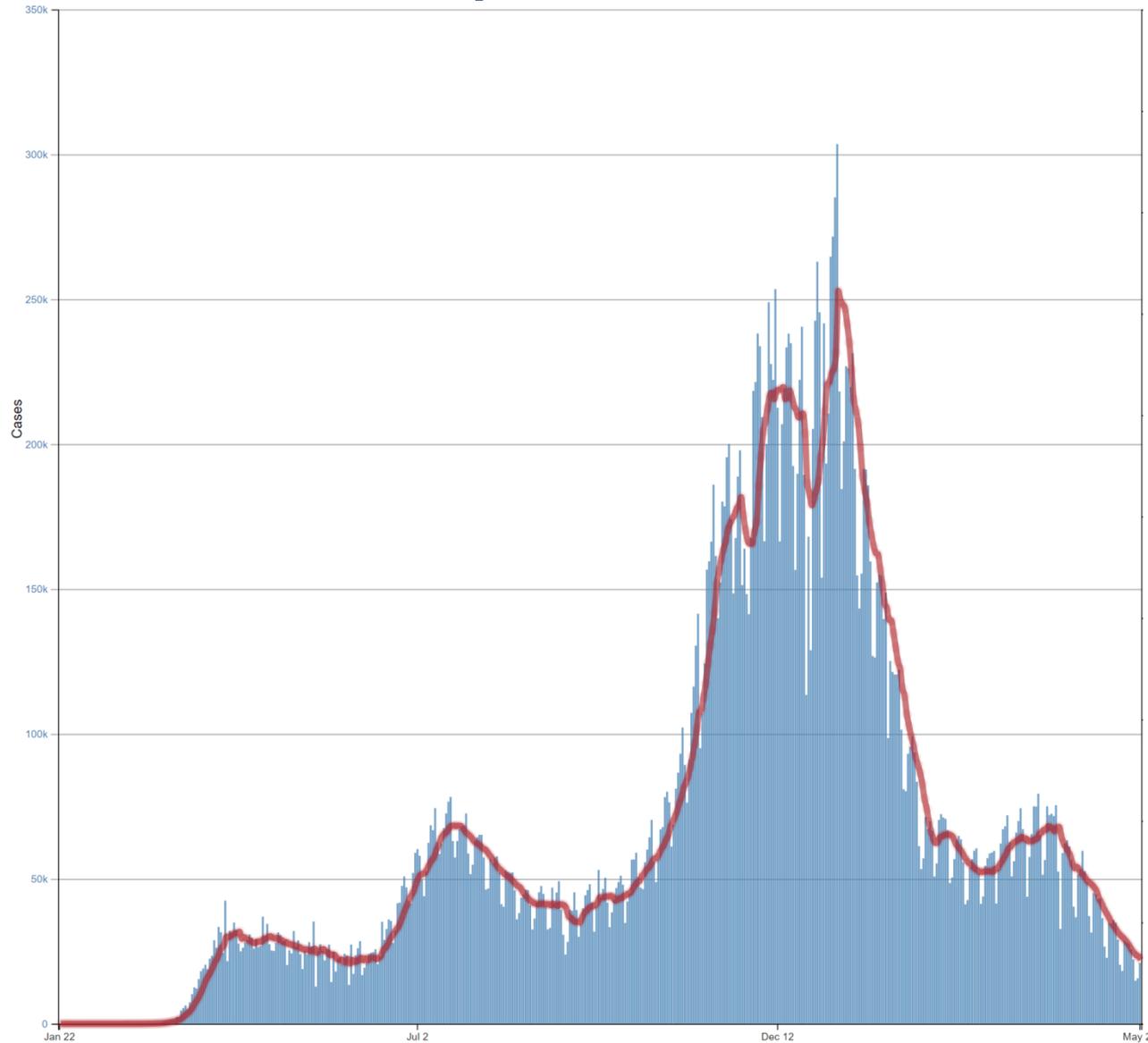
*Ben Chan  
Elizabeth Talbot  
Beth Daly  
Lindsay Pierce*

Thursday noon-time partner calls will focus on science, medical, and vaccine updates geared towards our healthcare partners

# Agenda

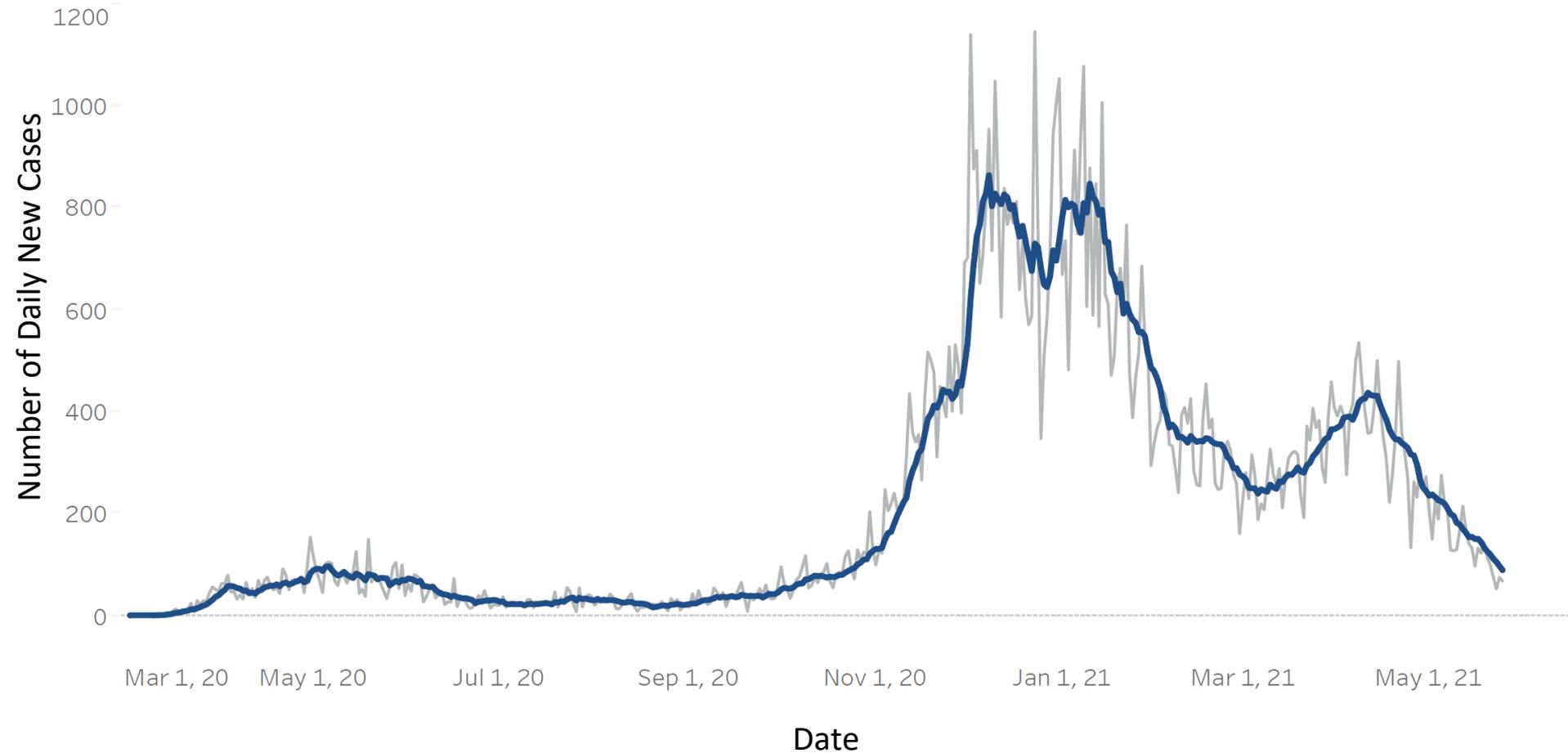
- Epidemiology update
- Myocarditis update: [VaST Work Group Technical Reports](#)
- CDC [Science Brief](#): COVID-19 vaccine efficacy and effectiveness (pending update)
- Moderna [Announcement](#) on TeenCOVE study results
- Novavax preliminary phase 3 clinical trial results ([medRxiv](#))
- Questions & Answers (Q&A)

# U.S. National Daily Incidence of COVID-19



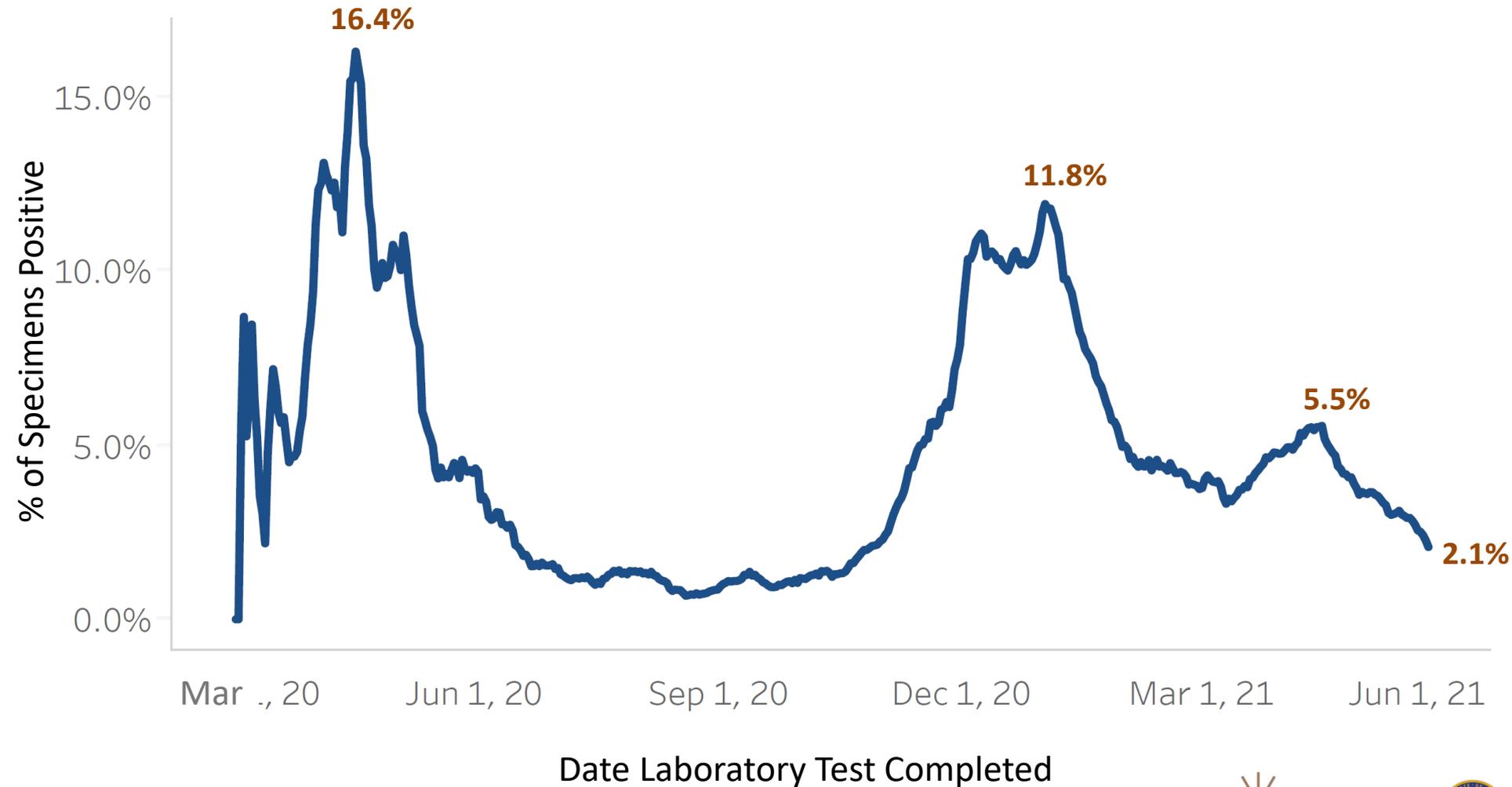
[https://covid.cdc.gov/covid-data-tracker/#trends\\_dailytrendscases](https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendscases)

# Number of New COVID-19 Cases per Day in NH



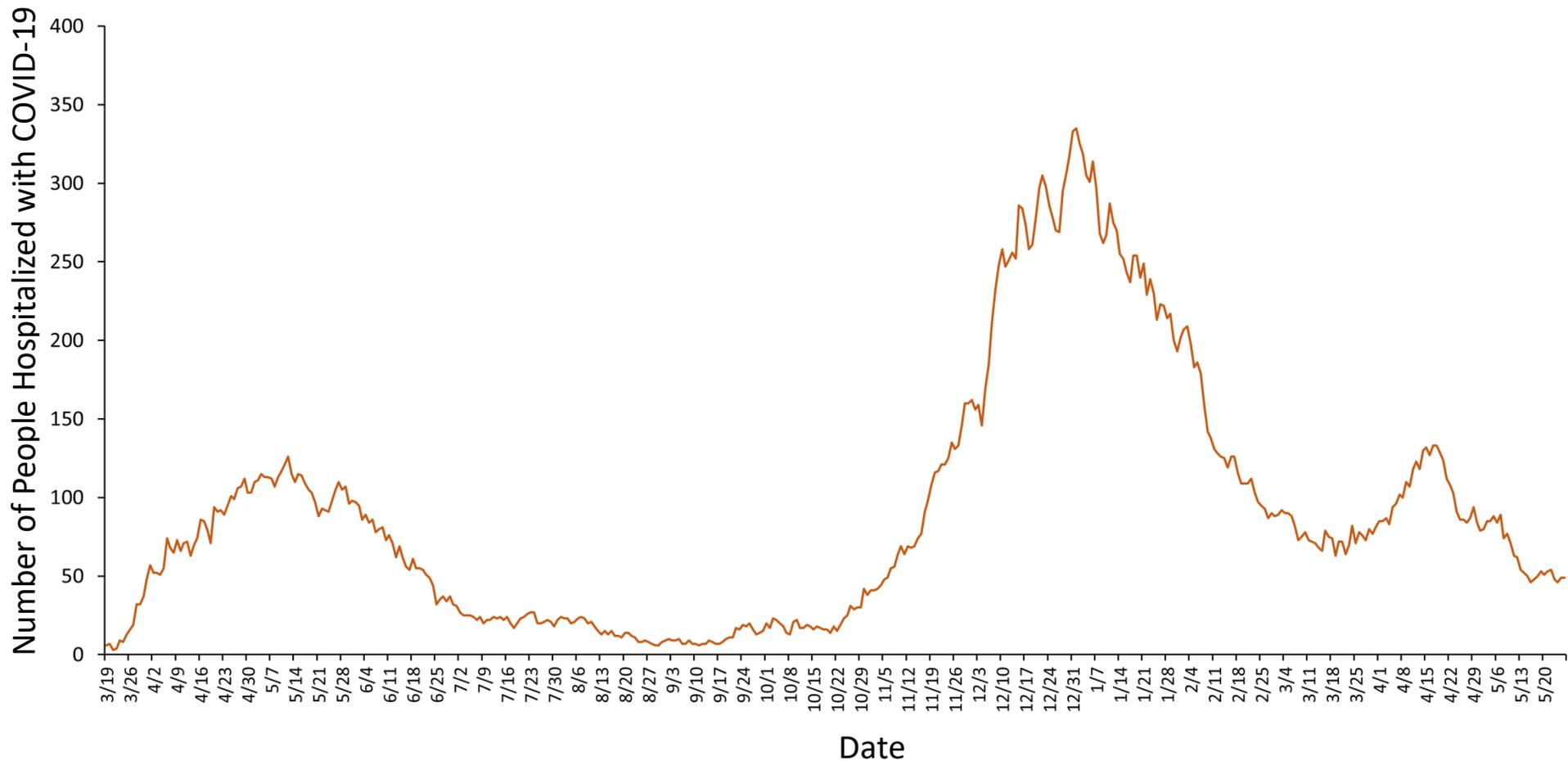
<https://www.nh.gov/covid19/dashboard/overview.htm#dash>

# % of Tests (Antigen and PCR) Positive for COVID-19 (7-Day Average)



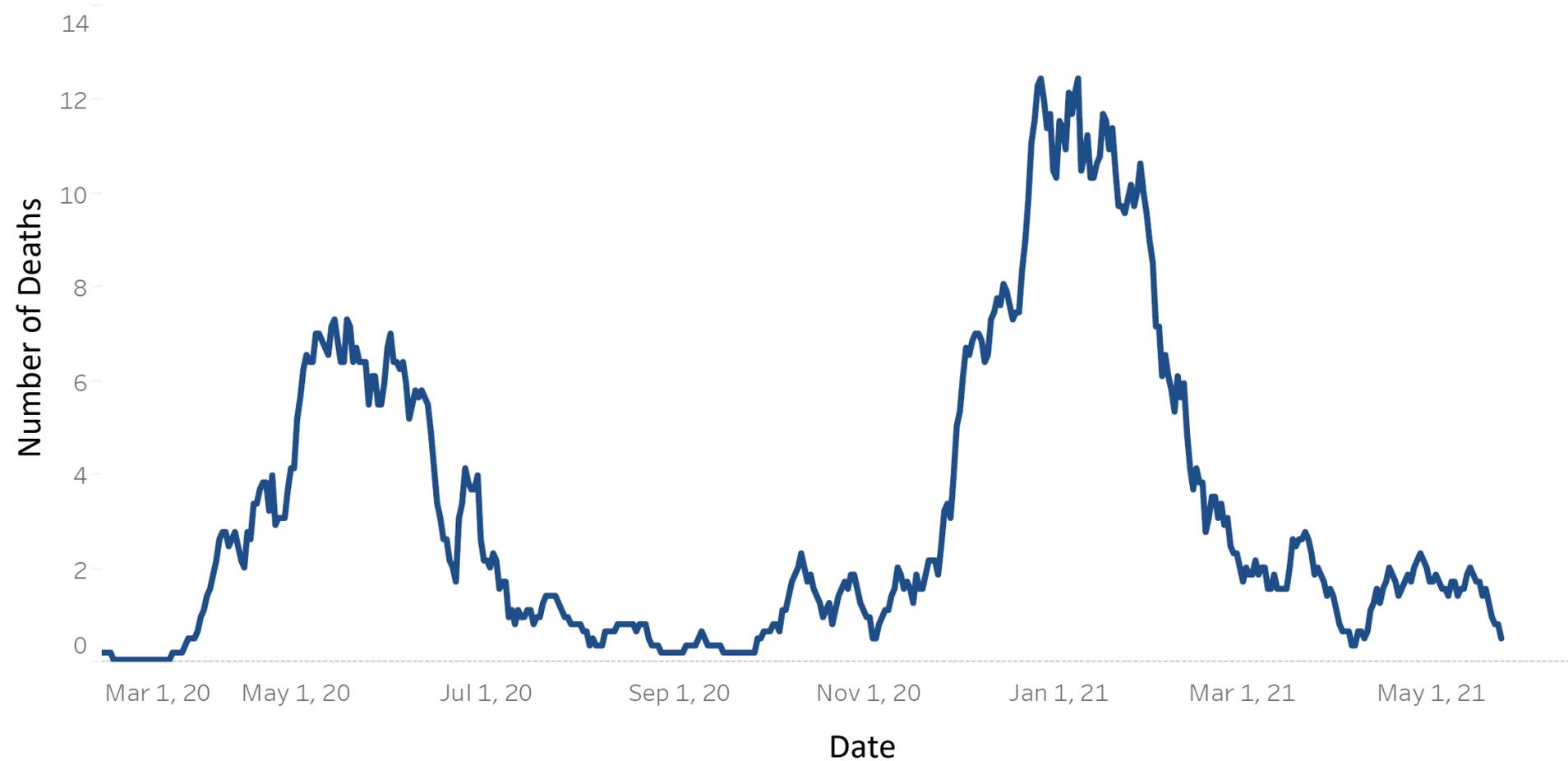
<https://www.nh.gov/covid19/dashboard/overview.htm#dash>

# Number of People Hospitalized with COVID-19 Each Day in NH (Hospital Census)



<https://www.nh.gov/covid19/dashboard/overview.htm#dash>

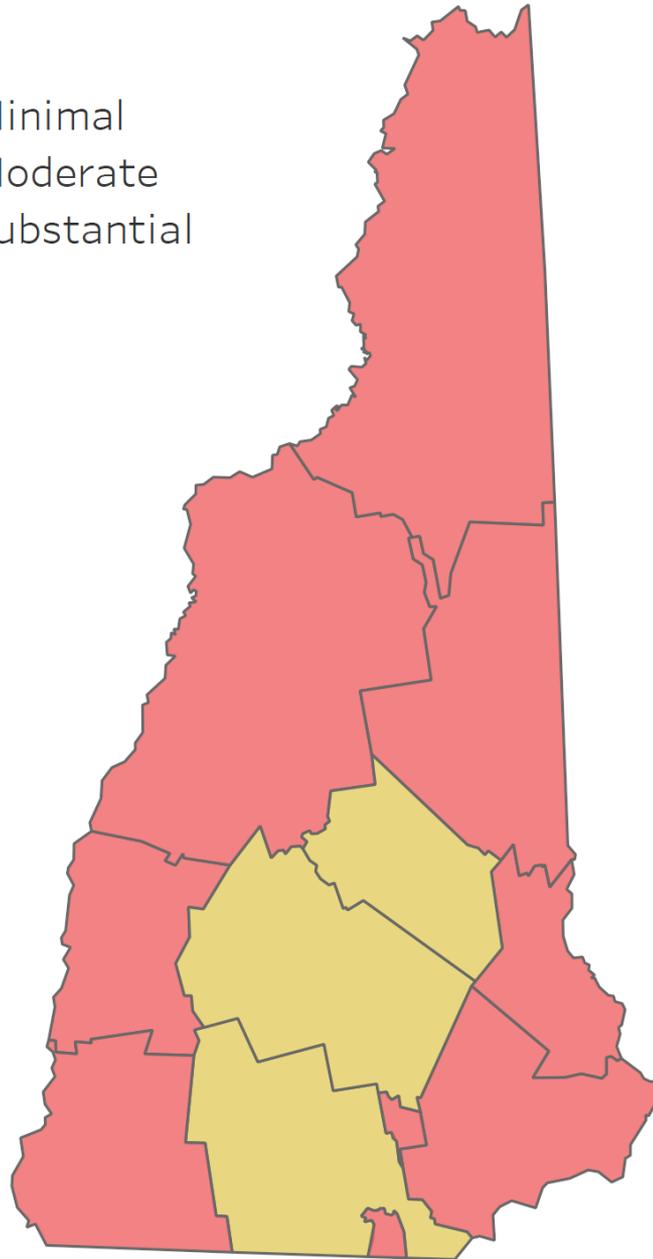
# Average Number of COVID-19 Deaths per Day in NH (Based on Date of Death)



<https://www.nh.gov/covid19/dashboard/overview.htm#dash>

# Level of Community Transmission

- Minimal
- Moderate
- Substantial



Level of  
Transmission

**Substantial**

New Cases per 100k  
over 14 days

**120.2**

7-Day Total Test  
Positivity Rate

**2.1%**

Data as of: 5/26/2021

<https://www.covid19.nh.gov/dashboard/schools>

# Myocarditis Update

# VaST Work Group Technical Report

- ACIP's COVID-19 Vaccine Safety Technical (VaST) Work Group has been reviewing COVID-19 vaccine safety data on a weekly basis
- Review of adverse event reports in two surveillance systems
  - [Vaccine Adverse Event Reporting System](#) (VAERS)
  - [Vaccine Safety Datalink](#) (VSD)
- There was not a safety signal identified at time of last VaST report (May 17<sup>th</sup>): reports of myocarditis after COVID-19 vaccination did not differ from expected baseline rates
  - Multiple causes of myocarditis, including: viral infections (cold viruses, COVID-19), bacterial infections (Lyme disease), etc.
- Providers should report events of myocarditis/pericarditis following COVID-19 vaccination into VAERS
- Further review, analysis and information pending from CDC

# Moderna's Preliminary TeenCOVE study results

## Moderna Announces TeenCOVE Study of its COVID-19 Vaccine in Adolescents Meets Primary Endpoint and Plans to Submit Data to Regulators in Early June

May 25, 2021

- Moderna's phase 2/3 TeenCOVE study enrolled 3,732 participants aged 12-17 years
- Randomized 2:1 to receive the Moderna COVID-19 vaccine (100 mcg dose) or placebo
- Immunogenicity was non-inferior compared to clinical trial adult comparator group
- Vaccine efficacy was 100% after 2 doses (0 cases in vaccine group vs. 4 cases in placebo group)
- No safety concerns identified
- Plan to submit data to FDA in early June

# Protein- Based (Protein Subunit) Vaccines

Acellular subunit vaccines that contain proteins but no genetic material

- Whole proteins or fragments
- Some on nanoparticles
- Some with adjuvants

All made using living organisms, such as bacteria and yeast, which require substrates on which to grow them, and strict hygiene to avoid contamination

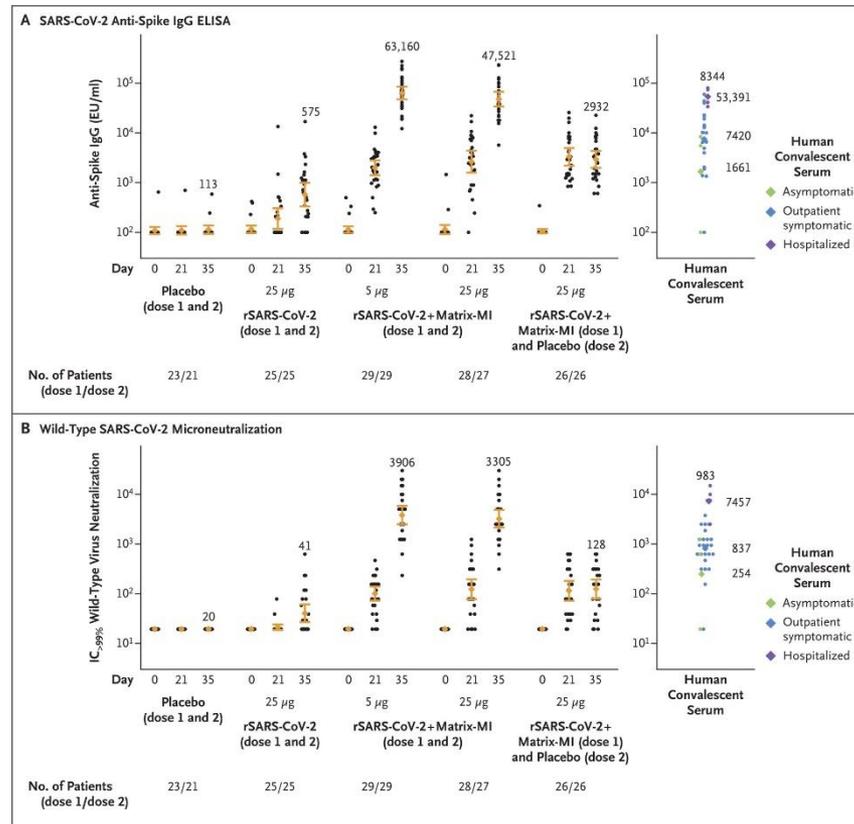
- More expensive to produce than mRNA vaccines

## Advantages

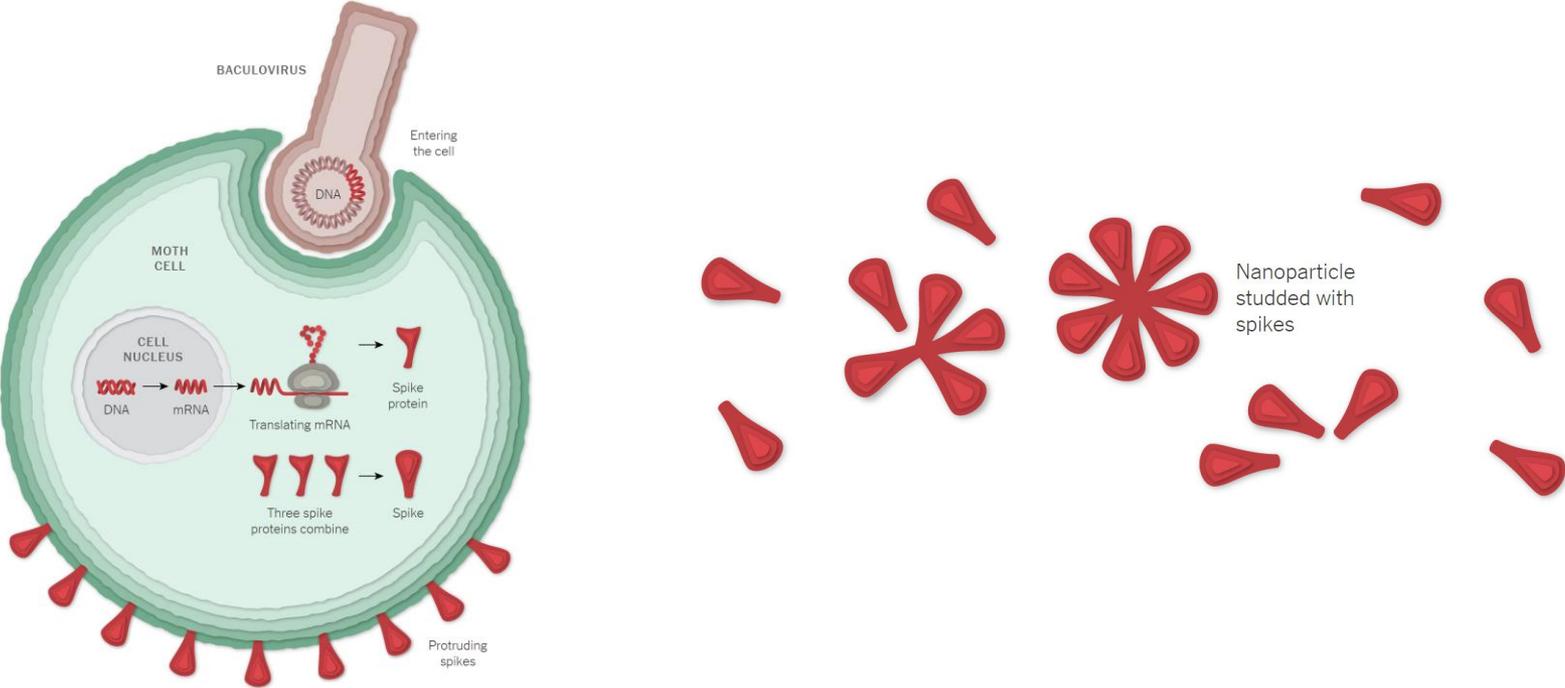
- Incapable of causing disease, very safe
- Suitable for people with compromised immune systems
- Stable
- Familiar: HBV, acellular pertussis

# Novavax

- Protein subunit vaccine, adjuvanted recombinant on nanoparticles
- 2-dose 21 days apart; stable 2-8°C; no diluent
- Preclinic and [phase 1/2 trials](#) in 131 participants showed IgG against spike protein exceeded natural infection; reactogenicity low and associated with adjuvant



# SARS-CoV-2 recombinant nanoparticle spike protein vaccine with Matrix-M adjuvant: NVX-CoV2373



Last Week

Sept  
Phase 3  
in 15k in  
UK

96% against original  
coronavirus

86% against B.1.1.7

49% against  
B.1.351 - modifying

# Novavax UK Phase 3 Published

- RCT, double-blind study in 18-84yo in 33 UK sites
- Excluded previous COVID-19, pregnancy, immuno-compromised
  - HIV on ARTs
- 400 received flu shot with dose 1

medRxiv  
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## Efficacy of the NVX-CoV2373 Covid-19 Vaccine Against the B.1.1.7 Variant

Paul T. Heath, Eva P. Galiza, David Neil Baxter, Marta Boffito, Duncan Browne, Fiona Burns, David R. Chadwick, Rebecca Clark, Catherine Cosgrove, James Galloway, Anna L. Goodman, Amardeep Heer, Andrew Higham, Shalini Iyengar, Arham Jamal, Christopher Jeanes, Philip A. Kalra, Christina Kyriakidou, Daniel F. McAuley, Agnieszka Meyrick, Angela M. Minassian, Jane Minton, Patrick Moore, Imrozia Munsoor, Helen Nicholls, Orod Osanlou, Jonathan Packham, Carol H. Pretswell, Alberto San Francisco Ramos, Dinesh Saralaya, Ray P. Sheridan, Richard Smith, Roy L. Soiza, Pauline A. Swift, Emma C. Thomson, Jeremy Turner, Marianne Elizabeth Viljoen, Gary Albert, Iksung Cho, Filip Dubovsky, Greg Glenn, Joy Rivers, Andreana Robertson, Kathy Smith, Seth Toback

doi: <https://doi.org/10.1101/2021.05.13.21256639>

**This article is a preprint and has not been peer-reviewed [what does this mean?]. It reports new medical research that has yet to be evaluated and so should *not* be used to guide clinical practice.**

# Defining the Primary Endpoint

---

Primary endpoint efficacy of NVX-CoV2373 against first occurrence of virologically confirmed symptomatic mild, moderate, or severe Covid-19, with onset at least 7 days after second vaccination in participants who were seronegative at baseline

---

Symptomatic Covid-19 was defined according to FDA criteria

---

Symptoms of suspected Covid-19 were monitored throughout the trial and collected using an electronic symptom diary for at least 10 days

---

At the onset of suspected symptoms, respiratory specimens from nose and throat collected daily over 3-day period to confirm infection and a clinical assessment was performed

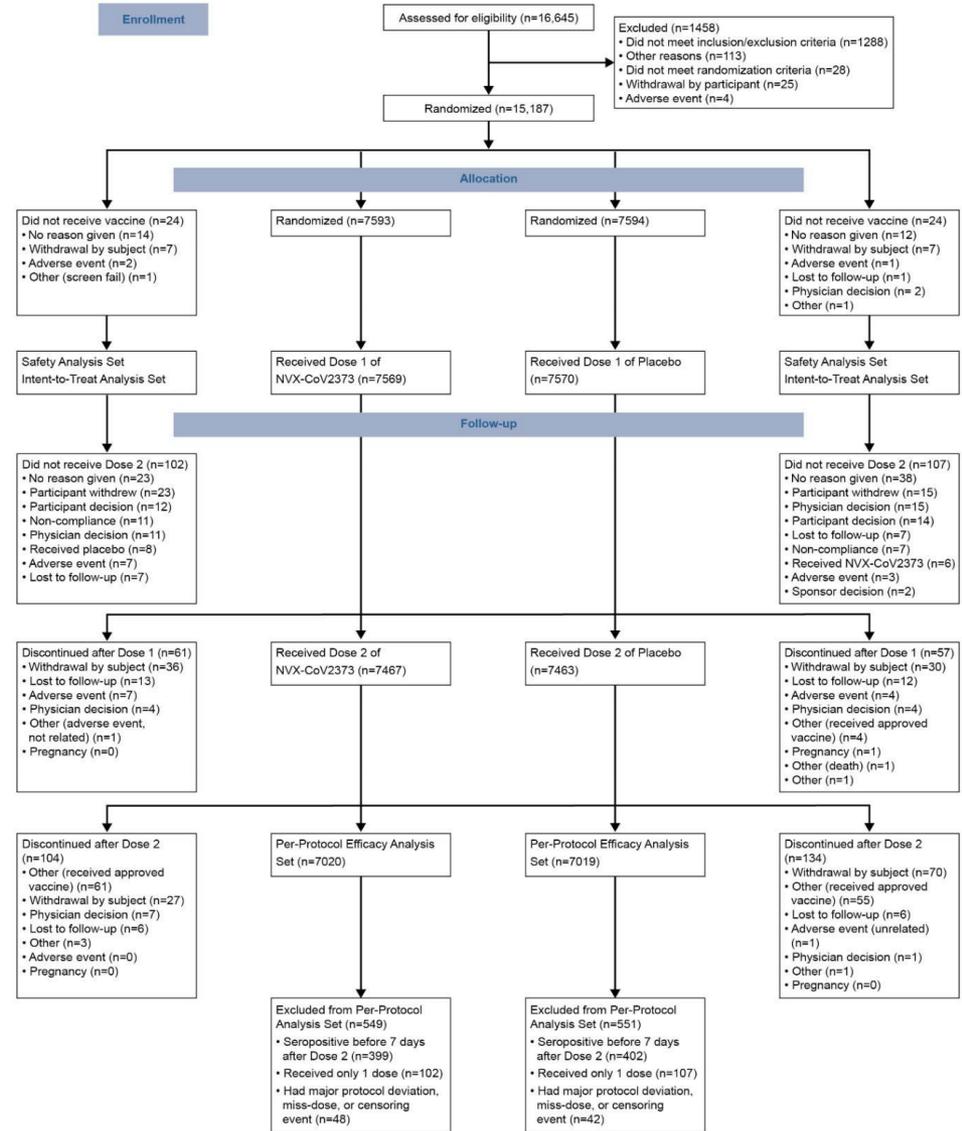
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Virological confirmation was performed using PCR

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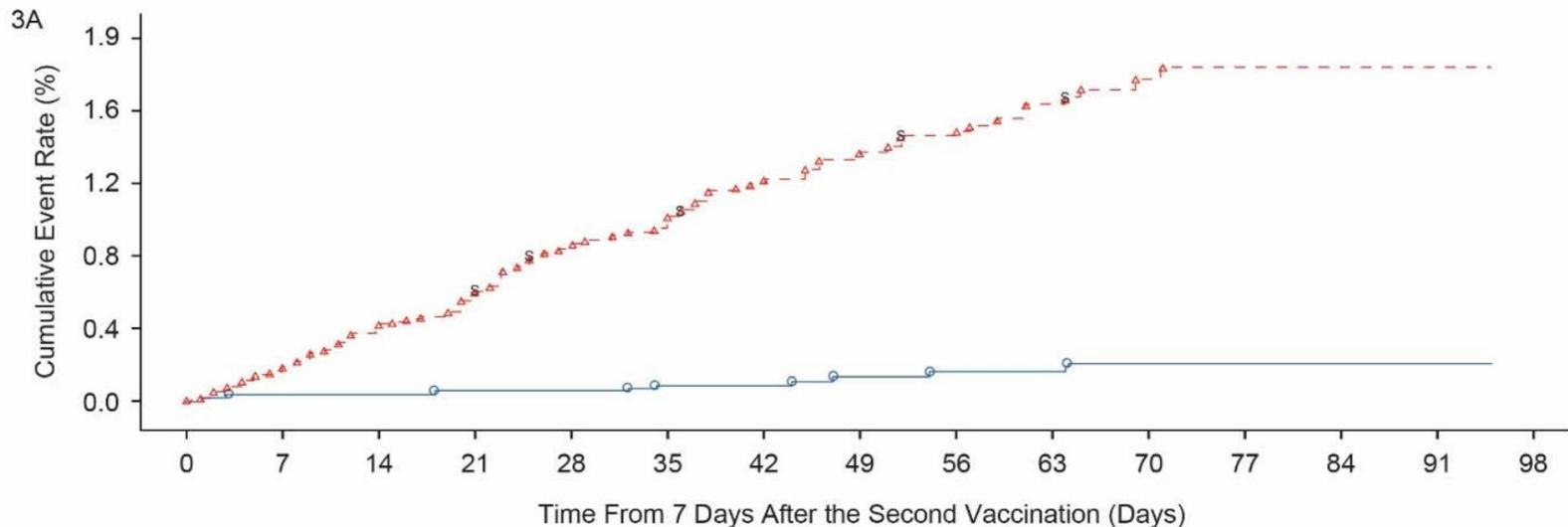
# Novavax UK Phase 3 Results

- Sept 28 – Nov 28 enrolled and randomized 15,187
  - 27.2% 65 or older
  - 44.7% with comorbidities
  - 4.2% Ab positive



# Per Protocol VE

- 10 cases in vaccinated, 96 among placebo: VE against virologically confirmed symptomatic COVID  $\geq 7$ d after 2<sup>nd</sup> shot 89.7% (95% CI, 80.2-94.6)
  - No hospitalizations or deaths in vaccine group; 5 severe in placebo
  - 96.4% (73.8-99.5) against original strain
  - 86.3% (71.3-93.5) against B.1.1.7
- VE among  $\geq 65$  years was 88.9% (95% CI, 12.8 to 98.6)
- VE from 14 days after dose 1 was 83.4% (95% CI, 73.6 to 89.5)



No. with event/No. at risk

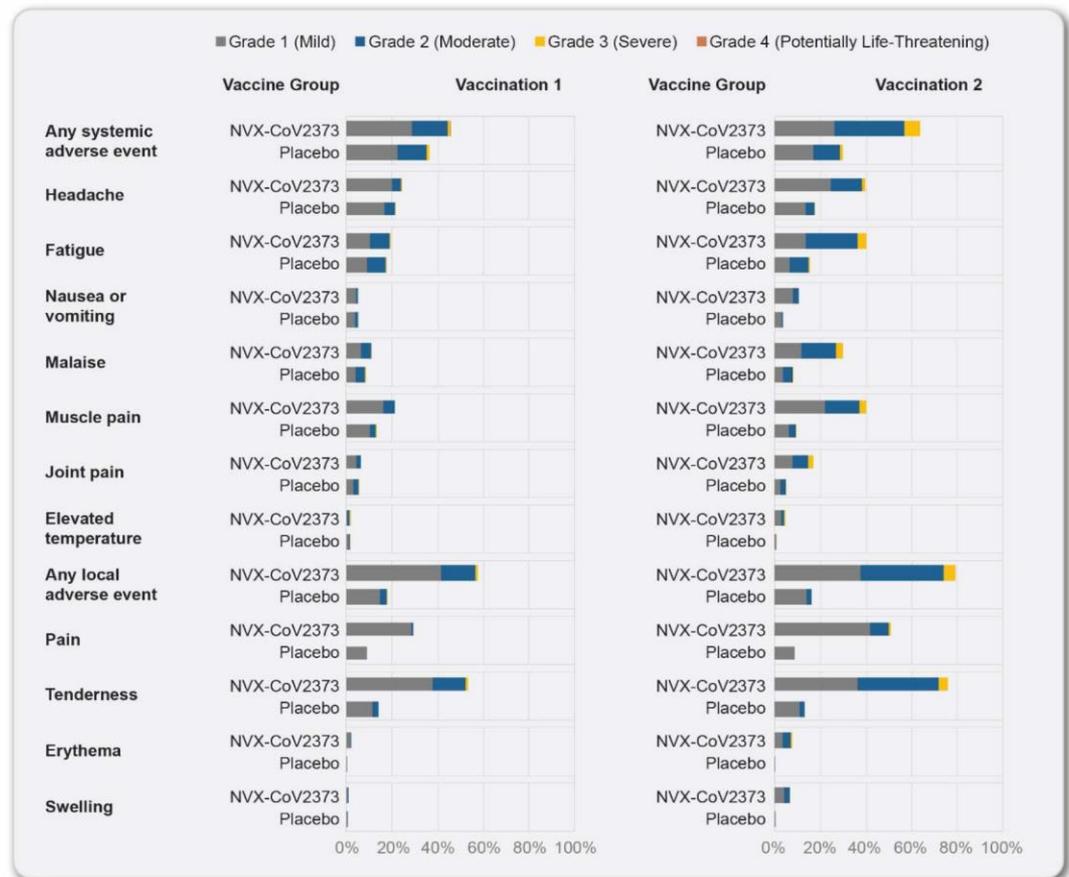
A:	0/ 7020	3/ 6989	3/ 6930	4/ 6847	4/ 6689	6/ 6343	6/ 5297	8/ 4342	9/ 3421	9/ 2664	10/ 1790	10/ 896	10/ 251	10/ 11	10/ 0
B:	1/ 7019	13/ 6978	28/ 6896	40/ 6777	57/ 6617	66/ 6260	77/ 5199	84/ 4269	88/ 3388	92/ 2629	95/ 1758	96/ 862	96/ 230	96/ 10	96/ 0

—○— A: NVX-CoV2373  
- -△- - B: Placebo



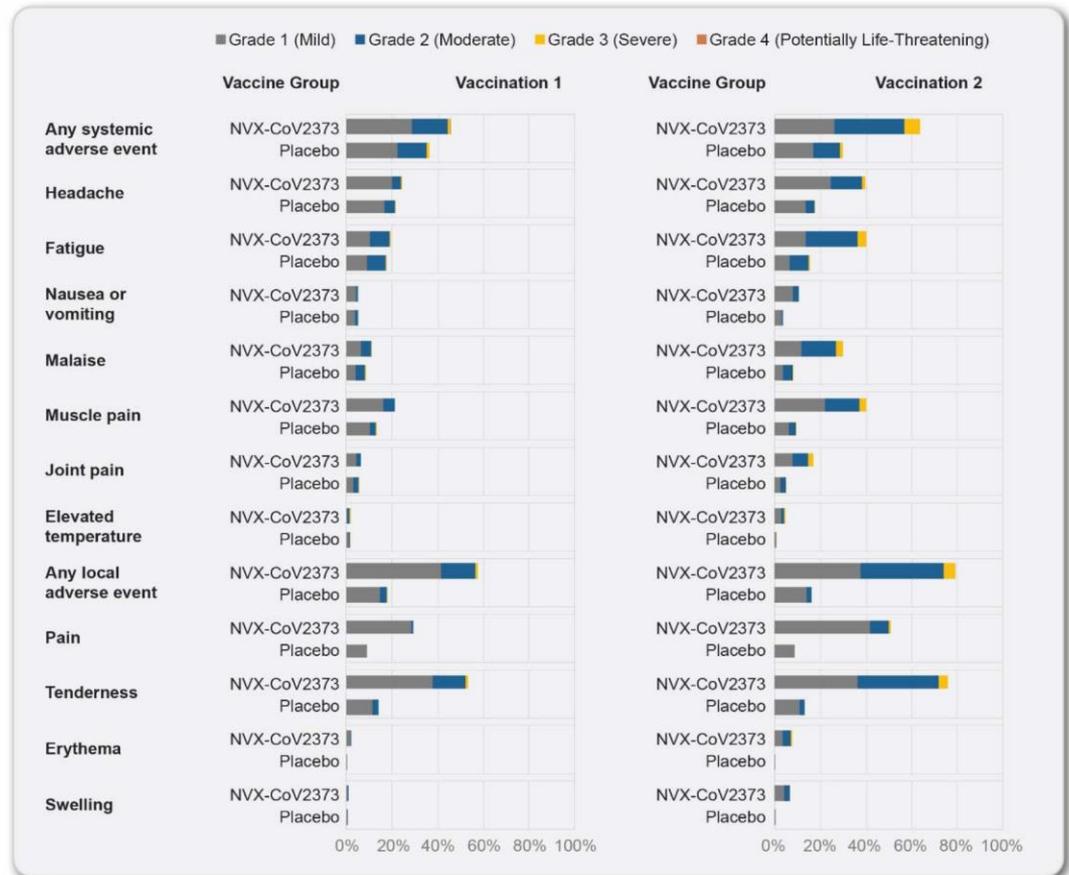
# Safety: Local AEs

- Among subgroup 2310 participants
- NVX-CoV2373 recipients reported more solicited local AEs than placebo
  - 1st dose 57.6% vs. 17.9%
  - 2<sup>nd</sup> dose 79.6% vs. 16.4%
- Most events mild or moderate and of short duration
  - 2.3 and 1.7 days after 1st
  - 2.8 and 2.2 days after 2nd
- More frequent among 18-64yo than older



# Safety: Systemic

- NVX-CoV2373 recipients reported higher frequencies of solicited systemic adverse events than placebo recipients
  - After 1st: 45.7% vs. 36.3%
  - After 2<sup>nd</sup> 64.0% vs. 30.0%
- Most events mild or moderate and of short duration
- Fever in 2.0% and 4.8% of NVX-CoV2373 participants after 1<sup>st</sup> and 2nd doses
- More frequent among 18-64yo than older



“One related serious adverse event was reported in an NVX-CoV2373 recipient (myocarditis), which occurred 3 days after the second dose and was considered a potentially immune-mediated condition; an independent SMC considered the event most likely a viral myocarditis. The participant recovered.”

# Novavax : US Timeline Update

Dec Phase 3 PREVENT-19 trial in 30k in 115 sites in US and Mexico of target populations

- Feb 22 completed enrolment
- May 3 announced including 3k 12-17 adolescents

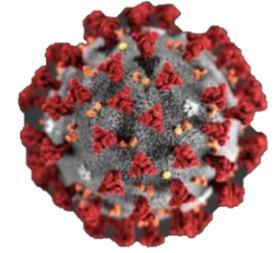
FDA EUA dossier expected May 2021

July shipping 1.1B doses to COVAX (GAVI, WHO, Coalition for Epidemic Preparedness Innovations)

# Cov-Boost Study

- UK study at 18 sites to inform UK's fall booster program
- Test 7 vaccines as booster doses for people  $\geq 30$ yo who are already fully vaccinated with two doses of a different authorized vaccine
  - AztraZeneca, Pfizer, Moderna, Novavax, Valneva, Curevac, Janssen plus control formulation
- May 19 began enrolling 2886 volunteers
  - Initial safety and immunologic results by September
  - Follow up 1y
- (Unique from ComCov which mixes first and second doses AZ and Pfizer)

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